



September 15, 2021

Possis Medical, Inc.
Frank Freedman
Senior Regulatory Affairs Associate
9055 Evergreen Blvd., N.w.
Minneapolis, Minnesota 55433-8003

Re: K071336

Trade/Device Name: XPEEDIOR Rheolytic Thrombectomy Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ,KRA

Dear Frank Freedman:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated August 24, 2007. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075,
Gregory.OConnell@FDA.HHS.gov.

Sincerely,

Gregory W.
O'Connell -S

Digitally signed by
Gregory W. O'Connell -S
Date: 2021.09.15
10:15:22 -04'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 24 2007

Possis Medical, Inc.
c/o Frank B. Freedman, Ph.D.
Senior Regulatory Affairs Associate
9055 Evergreen Boulevard NW
Minneapolis, MN 55433-8003

Re: K071336
XPEEDIOR™ Rheolytic Thrombectomy Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II (Two)
Product Code: DXE, KRA
Dated: July 18, 2007
Received: July 19, 2007

Dear Dr. Freedman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

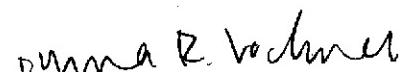
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 – Frank B. Freedman, Ph.D.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2

Indications for Use

510(k) Number (if known): K071336

Device Name: XPEEDIOR™ Rheolytic Thrombectomy Catheter

Indications For Use: The AngioJet XPEEDIOR 120 Rheolytic Thrombectomy Catheter is intended for use with the AngioJet System in breaking apart and removing thrombus from:

- infra-inguinal peripheral arteries \geq 3.0 mm in diameter,
- upper extremity peripheral veins \geq 3.0 mm in diameter and
- iliofemoral and lower extremity veins \geq 3.0 mm in diameter.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Janna R. Winkler
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) number K071336

K071336
p. 1 of 1

5. 510(k) Summary

Submitter: Frank B. Freedman, Ph.D.
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9055 Evergreen Boulevard, N.W.
Coon Rapids, MN 55433
Phone: 763.780.4555
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AUG 24 2007

Contact Person:	<u>Primary Contact</u>	<u>Secondary Contact</u>
	Frank B. Freedman	Mark D. Stenoien
	Possis Medical, Inc.	Possis Medical, Inc.
Device Common Name:	Thrombectomy Catheter	
Device Trade Name:	XPEEDIOR™ Rheolytic Thrombectomy Catheter	
Device Classification Name:	Embolectomy Catheter	
Predicate Devices:	AngioJet XPEEDIOR® Rheolytic™ Thrombectomy Catheter (K040013, K052256 and K061951)	

Device Description

When used with the AngioJet System, the XPEEDIOR Rheolytic Thrombectomy Catheter uses high velocity saline jets to percutaneously break-up and remove thrombus. These saline jets are contained within the Catheter and provide the suction that produces this effect.

Indications for Use

The currently cleared XPEEDIOR Catheter indications for use were expanded to include breaking apart and removing thrombus from:

- infra-inguinal peripheral arteries \geq 3.0 mm in diameter,
- upper extremity peripheral veins \geq 3.0 mm in diameter and
- iliofemoral and lower extremity veins \geq 3.0 mm in diameter.”

Comparison to Predicate Devices

No design, packaging, sterilization or other device change was required to expand the AngioJet XPEEDIOR Rheolytic Thrombectomy Catheter indications for use (K040013, K052256 and K061951).

Supporting Information

Applicable preclinical and clinical experience support the expanded indications for use.